# BOARD OF PHARMACY PROPOSED ADDITION TO TITLE 16, DIVISION 17 CCR Citation and Fine for Patient Privacy Violations & Internet Dispensing Violations

Add Article 9.6 to Title 16, Chapter 17 of the California Code of Regulations.

## **Article 9.6 Citation and Fine – Patient Privacy Violations**

## **Section 1777 -- Authority to Issue Citations**

- (a) A committee of the board may issue citations against a licensee containing orders of abatement and fines for the disclosure of medical information in violation of the Confidentiality of Medical Information Act (Commencing with Section 56 of the Civil Code). Any citation issued for the willful disclosure of medical information for financial gain shall be accompanied by an order of abatement that requires the disgorgement of any proceeds or other consideration obtained as a result of the violation. For the purposes of this article, "committee of the board" means a committee of board members appointed by the board president to consider investigations of alleged violations. (b) Each citation shall be in writing and shall describe with particularity the nature and facts of
- (b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the licensee personally or by certified mail.
- (c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. Payment of any fine shall not constitute an admission of the violation charged.
- (d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A licensee shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that hearing. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.

Authority: Section 4005 Business and Professions Code, Section 56.36 Civil Code Reference: Section 56.36 Civil Code, Section 4301 Business and Professions Code

# **Section 1777.1 -- Amount of Fines for Violations by Pharmacists**

- (a) Any pharmacist, who negligently discloses medical information in violation of the provisions the Confidentiality of Medical Information Act shall be subject, irrespective of the amount of damages suffered by the patient as a result of that violation, to an administrative fine not to exceed two thousand five hundred dollars (\$2,500) per violation.
- (b) A pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act shall be subject on a first violation, for an administrative fine not to exceed two thousand five hundred dollars (\$2,500) per

violation, or on a second violation for an administrative fine not to exceed ten thousand dollars (\$10,000) per violation, or on a third and subsequent violation for an administrative fine not to exceed twenty-five thousand dollars (\$25,000) per violation.

- (c) A pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act for financial gain shall be liable on a first violation, for an administrative fine not to exceed five thousand dollars (\$5,000) per violation, or on a second violation for an administrative fine not to exceed twenty-five thousand dollars (\$25,000) per violation, or on a third and subsequent violation for an administrative fine not to exceed two hundred fifty thousand dollars (\$250,000) per violation.
- (d) Nothing in this subdivision shall be construed as authorizing an administrative fine under both this section and section 1777.2 for the same violation.

Authority: Section 4005 Business and Professions Code, Section 56.36 Civil Code Reference: Section 56.36 Civil Code, Section 4301 Business and Professions Code

# Section 1777.2 – Amount of Fines for Violations by Non-Professional Licensees

- (a) Any person or entity licensed by the board, other than a pharmacist, that negligently discloses medical information in violation of the provisions the Confidentiality of Medical Information Act shall be subject, irrespective of the amount of damages suffered by the patient as a result of that violation, to an administrative fine not to exceed two thousand five hundred dollars (\$2,500) per violation.
- (b) Any person or entity licensed by the board, other than a pharmacist, who knowingly and willfully obtains, discloses, or uses medical information in violation of the Confidentiality of Medical Information Act shall be subject to an administrative fine not to exceed twenty-five thousand dollars (\$25,000) per violation.
- (c) Any person or entity licensed by the board, other than a pharmacist, who knowingly or willfully obtains or uses medical information in violation of the Confidentiality of Medical Information Act for the purpose of financial gain shall be liable for an administrative fine not to exceed two hundred fifty thousand dollars (\$250,000) per violation.
- (d) Nothing in this subdivision shall be construed as authorizing an administrative fine or civil penalty under both this section and section 1777.1 for the same violation.

Authority: Section 4005 Business and Professions Code, Section 56.36 Civil Code Reference: Section 56.36 Civil Code, Section 4301 Business and Professions Code

# **Section 1777.3 -- Factors Considered in Assessing Fines**

In assessing the amount of an administrative fine pursuant to section 1777.2, the committee of the board shall consider any one or more of the relevant circumstances presented by any of the parties to the case including, but not limited to, the following:

- (1) Whether the respondent has made a reasonable, good faith attempt to comply with the Confidentiality of Medical Information Act (Civil Code Section 56 et seq.).
- (2) The nature and seriousness of the misconduct.
- (3) The harm to the patient.
- (4) The number of violations.
- (5) The persistence of the misconduct.

- (6) The length of time over which the misconduct occurred.
- (7) The willfulness of the defendant's misconduct.
- (8) The defendant's assets, liabilities, and net worth.

Authority: Section 4005 Business and Professions Code, Section 56.36 Civil Code Reference: Section 56.36 Civil Code, Section 4301 Business and Professions Code

## **Section 1777.4 --. Compliance With Orders of Abatement**

- (a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request an extension of time in which to complete the correction from the board. Such a request shall be in writing and shall be made within the time set forth for abatement.
- (b) An order of abatement shall either be personally served or mailed by certified mail. The time allowed for the abatement of a violation shall begin when the order of abatement is final and has been served or received.
- (c) Failure to abate the violation within the time frame specified in the order of abatement, shall constitute a ground for revocation or suspension of the license, permit, or registration. When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement.
- (d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Authority: Section 4005 Business and Professions Code, Section 56.36 Civil Code Reference: Section 56.36 Civil Code, Sections 125.9 and 4301 Business and Professions Code

#### **Section 1777.5 -- Contested Citations**

Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals under this article shall be conducted in accordance with Section 4300 (e) of the Business and Professions Code.

Authority: Section 4005 Business and Professions Code, Section 56.36 Civil Code Reference: Section 56.36 Civil Code, Section 4301 Business and Professions Code

#### **Cite and Fine for Internet Violations**

Add Article 9.8 to Title 16, Chapter 17 of the California Code of Regulations.

# **Article 9.8 Citation and Fine – Internet Dispensing Violations**

**Section 1778 – Authority to Issue Citations** 

- (a) A committee of the board may issue citations containing orders of abatement and fines for dispensing or furnishing, or causing to be dispensed or furnished, dangerous drugs or dangerous devices, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination, or if the person or entity did not act in accordance with Section 1761. For the purposes of this article, "committee of the board" means a committee of board members appointed by the board president to consider investigations of alleged violations.
- (b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the licensee personally or by certified mail.
- (c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the citation and/or fine, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. Payment of any fine shall not constitute an admission of the violation charged.
- (d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A licensee shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that meeting. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.

Authority: Section 4005 Business and Professions Code Reference: Section 4067 Business and Professions Code

# **Section 1778.1 – Factors Considered in Assessing Fines**

Fines issued pursuant to this article shall not exceed \$25,000 per violation. In assessing the amount of an administrative fine, the committee of the board shall give due consideration to the following factors:

- (a) The gravity of the violation.
- (b) The good or bad faith of the cited person or entity.
- (c) The history of previous violations.
- (d) Evidence that the violation was or was not willful.
- (e) The extent to which the cited person or entity has cooperated with the board's investigation.
- (f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- (g) Other matters as may be appropriate.

Authority: Section 4005 Business and Professions Code Reference: Section 4067 Business and Professions Code

# **Section 1778.2 – Compliance With Orders of Abatement**

- (a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request an extension of time in which to complete the correction from the board. Such a request shall be in writing and shall be made within the time set forth for abatement.
- (b) An order of abatement shall either be personally served or mailed by certified mail. The time allowed for the abatement of a violation shall begin when the order of abatement is issued.
- (c) When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement. Such failure shall constitute a ground for revocation or suspension of the license, permit, or registration.
- (d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Authority: Section 4005 Business and Professions Code

Reference: Sections 125.9 and 4067 Business and Professions Code

## **Section 1778.3 – Contested Citations**

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Authority: Section 4005 Business and Professions Code Reference: Section 4067 Business and Professions Code